

respect to the anatomy of the patient, for example to guide in drilling a hole for insertion of a spinal fixation screw.

### The Present Invention

Image guided surgery systems similar to those described in Kalfas are used for various medical procedures. A drawback to these systems, however, is that it may be difficult for the surgeon to visualize, with reference to the data displayed on the monitor, the manipulation required to place the tool in the desired position and orientation.

The surgeon is forced to visualize the position of the tool with respect to the displayed image and relate that information to a required movement of the tool in relation to the patient. This task is complicated by the three dimensional nature of the required manipulation, the two dimensional nature of the displayed images, and the often disparate positions of the monitor and patient. The present invention provides an apparatus and method which helps simplify the required visualization. As will be appreciated, neither the problem or its solution is recognized or suggested by Kalfas.

Independent **claim 1** has been amended to require that the means for indicating the difference between the desired and actual positions of the tool provide an indication useful to a human. Claim 1 has also been amended to require a means for determining an actual position of the means for indicating.

In paragraphs 4 and 5 of the office action, the Examiner has indicated that Kalfas' emitters 48, 50 indicate a difference between the actual and desired positions of the tool. In fact, the emitters 48, 50 provide a signals indicative only of the actual position of the tool with respect to the receivers 14. Even then, this information is not provided in a form understandable to a human. Only after further processing by a localizer system and with additional information (such as the desired position, the relative relationships between the various reference frames, and the like) can the difference between the actual and desired positions be displayed in human readable form on the monitor 30. To clarify any confusion as to the distinction between Kalfas'

emitters 48, 50 and the means for indicating of the present claim 1, the first element has been amended to require that the means for indicating provide the information in a form understandable to a human.

Amended claim 1 also requires a means for determining an actual position of the means for indicating. Kalfas fails to disclose or suggest such a requirement, teaching only that the monitors be placed so as to be visible to the user.

Independent **claim 17** has been amended to require that at least one position indicator be mounted to the surgical tool and that the indicator provide to a human operator an indication of the direction in which the tool should be moved to reach a desired position.

Kalfas teaches that its monitors 30 be placed on a stand, suspended from the ceiling, or the like. As described more fully above with respect to claim 1, the emitters 48, 50 of Kalfas provide machine-readable signals indicative of the actual position of the tool, as opposed to a human readable indication of the direction in which the tool should be moved to reach the desired position. Kalfas thus fails to disclose or suggest the human readable, tool mounted, directional indicator of claim 17.

Like claim 17, independent **claim 24** requires that the indicator be mounted to the tool, and that the indicator provide an indication of the difference between the actual positions. Again, Kalfas fails to suggest a tool mounted indicator which indicates of the difference between the actual and desired positions. Inasmuch as claim 24 also requires a means for determining an actual position of the tool, it will again be appreciated that the tool mounted indicator of present claim 24 is to be distinguished for the emitters 48, 50 of Kalfas.

Independent **claim 25** is directed to a surgical tool having a plurality of infrared emitters mounted to the tool and at least one position indicator mounted to the tool. Claim 25 has been amended to require that the position indicator provide a visual, audible, or other human readable indication. While Kalfas indeed discloses tool-mounted sonic or infrared emitters for providing a

signal to an appropriate localizer, it fails to disclose or suggest that a human readable position indicator also be mounted to the tool.

Independent **claim 26** has been amended, *inter alia*, to add the steps of (i) determining the actual position of a position indicator having an indicator reference frame; and (ii) utilizing the position indicator to indicate to a human the direction in which the tool must be moved to reach the desired position, with the indication being provided in relation to the indicator reference frame.

Kalfas fails to disclose or suggest that the actual position of its monitors 30 be determined or that the indication being provided in relation to the indicator reference frame. Similarly, Kalfas's emitters 48, 50 do not indicate to a human the direction in which the tool must be move to reach the desired position.

Accordingly, it is respectfully submitted that independent claims 1, 17, 24, 25, and 26 distinguish patentably and unobviously over the prior art of record. In view of such non-obviousness and the distinctions between the present invention and Kalfas, it is likewise submitted that the double patenting<sup>1</sup> and 35 U.S.C. § 102(f) rejections have been addressed.

Dependent **claims 7, 20, 27, 28, 30, and 31** have been amended for the sake of consistency in view of the amendments to their respective independent claims. **Claim 12** has been amended to address a minor informality.

**Claim 2**, which is dependent from claim 1, requires that the tool be characterized by a tool reference frame and that the difference between the actual and desired positions of the tool be indicated in relation to the tool reference frame. Kalfas, which teaches simply that the position of the tool is displayed on the monitor, fails to disclose or suggest such a requirement.

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<sup>1</sup> The present application is assigned to Picker International, Inc., while Kalfas is assigned to The Cleveland Clinic Foundation. While Picker International has certain license rights in and to the Kalfas patent, the two properties are not commonly assigned. This provides a basis for withdrawal of the double patenting rejection separate and apart from the substantive reasons set forth above.

Claim 3, which depends from claim 2, requires a tool-mounted means for indicating to a human the difference between the actual and desired positions. Claims 30 and 31 also require a tool-mounted indicator. As discussed above, Kalfas fails to disclose such a tool mounted indicator.

Claim 19, which depends from claim 17, requires that the direction in which the tool should be moved be indicated with respect to the indicator reference frame. In Kalfas, the indication is unrelated to the reference frame of the monitors. Accordingly, Kalfas fails to disclose or suggest such a requirement.

Claim 20, which depends from claim 19, requires a means for determining the relative orientations of the human understandable indicator and the anatomy of the patient. Claim 28, a method claim depending from claim 26, requires the steps of determining the relative orientations of the indicator and the patient and compensating for changes in relative orientation. Kalfas fails to disclose or suggest that the relative orientation of the display and patient be considered, let alone compensating for changes in the relative orientation.

For at least the reasons set forth above, together with their dependence from their respective independent claims, it is submitted that claims 2-15, 19-23, and 27-31 and 33-35 are directed to patentable subject matter.

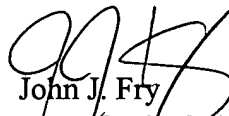
Claims 18 and 32 have been canceled.

A one month petition for extension of time, together with a check for the requisite fee, is also enclosed herewith.

### **Conclusion**

In view of the foregoing, it is respectfully submitted that claims 1-17, 19-31, and 33-35 distinguish patentably and unobviously over the prior art of record. An early indication of allowability is earnestly solicited.

Respectfully submitted,



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